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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,962	02/16/2001	Gordon Moore Allan	454313-2338.1	6400
20999	7590	04/22/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			FOLEY, SHANON A	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 04/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/784,962

Applicant(s)

ALLAN ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40,42-45 and 68-86 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 38,40,42-45 and 68-86 is/are rejected.
7) ☒ Claim(s) 38,40 and 42-45 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/347,594.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In the paper filed January 22, 2004, applicant amended claims 38, 40, 42-45 and 69-85. Claims 1-37, 39, 41 and 46-67 are cancelled. Claims 38, 40, 42-45 and 68-86 are pending and under consideration.

Terminal Disclaimer

The terminal disclaimer filed on January 22, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,217,883 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claims 38 is objected to because of the following informalities: While it is clear from the record that the protective antigen referred to in the claim is an inactivated porcine type II circovirus, it is not completely evident from the claim language, since an "antigen" can be a pathogenic agent or any portion thereof. This objection also affects claims 40 and 42-45. Appropriate correction is required. Applicant may easily overcome this objection by deleting "antigen" in claim 38.

Claim 42 is objected to for the same informalities discussed above for claim 38. Since it is clear from the record that the porcine circovirus type II protective antigen referred to is an inactivated virus, the claim needs to be amended to eliminate any possible ambiguity. Appropriate correction is required. Applicant may also easily overcome this objection by amending the claim to recite: "The vaccine of claim 38, wherein the porcine circovirus type II is

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at least one porcine circovirus type II deposited at the ECACC and is selected from the group consisting of..."(followed by the language in the rest of the claim).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38, 40, 42-45 and 68-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,517,843 (Ellis et al.) in view of Meyers et al. (U.S. Patent No. 5,811,103).

The claims are drawn to a vaccine and a composition comprising an inactivated porcine circovirus type II and a parvovirus antigen.

Ellis et al. claim a composition comprising an inactivated PCV-2. Ellis et al. do not claim that the composition additionally comprises a porcine parvovirus antigen.

Meyers et al. claim a vaccine for a hog cholera virus, see claim 9. Meyers et al. additionally teach that the vaccine can be combined with other porcine immunogens, such as parvovirus, see column 6, lines 8-13.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the inactivated PCV-II of Ellis et al. with other porcine antigens, such as

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parvovirus to form and administer a multivalent vaccine. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing a multivalent porcine vaccine by conventional methods in the art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Claims 85 and 86 are drawn to a kit comprising a porcine circovirus type II antigen packaged separately with a porcine parvovirus.

See the teachings of Ellis et al. and Meyers et al. above. Neither reference teaches a kit comprising at least two antigenic components. However, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the different porcine immunogens of Ellis et al. and Meyers et al. into the same proximity within a kit to mix different quantities of the immunogens together to obtain a single immunogenic formulation.

Claims 38, 40, 42-45 and 68-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-16, 18, 23 and 26 of U.S. Patent No. 6,660,272 (Allan et al.), in view of Meyers et al. (U.S. Patent No. 5,811,103).

Allan et al. claim an immunogenic composition comprising an isolated porcine circovirus type II immunogen. Allan et al. do not claim that the composition additionally comprises a porcine parvovirus antigen.

Meyers et al. claim a vaccine for a hog cholera virus, see claim 9. Meyers et al. additionally teach that the vaccine can be combined with other porcine immunogens, such as parvovirus, see column 6, lines 8-13.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the inactivated PCV-II of Allan et al. with other porcine antigens, such as parvovirus to form and administer a multivalent formulation. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing a multivalent porcine formulation by conventional methods in the art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Claims 85 and 86 are drawn to a kit comprising a porcine circovirus type II antigen packaged separately with a porcine parvovirus.

See the teachings of Allan et al. and Meyers et al. above. Neither reference teaches a kit comprising at least two antigenic components. However, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the different porcine immunogens of Allan et al. and Meyers et al. into the same proximity within a kit to mix different quantities of the immunogens together to obtain a single immunogenic formulation.

Conclusion

Applicant has amended the claims and pointed to distinctions between the inventive concepts in the response. The only issue unresolved by applicant's response is the enablement of sufficient attenuation of PCV. However, Terpestra et al. (Vaccine. 1996; 14 (6): 570-575), reviews various conventional protocols for determining the efficacy and the potency of live viral vaccines for veterinary use, including a couple of pig vaccines, see Table 1 on page 574. Therefore, considering the plethora of techniques available to the skilled artisan to determine

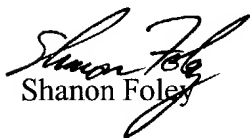
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sufficient attenuation, it is determined that sufficient attenuation of PCV would not require an undue quantity of experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley